K110345

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

OCT 19 2011

Device & Establishment name, Registration Number and submission details.

Proprietary Device Name: ScanView

Name: Applied Spectral Imaging Ltd.. (ASI hereafter) Registration: 9615060

Submission contact: Dan Laor Sireni 6, Haifa 32972, Israel TEL: 972-4-8246632

Device Classification

Product Code:	NTH
Regulation Number:	866.4700
Regulation Description:	Automated fluorescencein situhybridization (FISH) enumeration system.
Device class:	II

Reason for 510(k) Submission

Traditional 510(k). Expansion of the indications for use, by adding Bladder Tests.

Identification of Legally Marketed Equivalent Devices

ScanView k101291 Duet System k050840

Device Description

The ScanView is an integrated digital imaging system constructed of an external microscope, motorized multi slide stage, camera, and a workstation. It is designed to acquire images of cells and enables identification and examination of cells of interest. Experts can view and scan cells and record the image, using both bright field and fluorescent illumination. The acquired images can be enhanced, archived, retrieved and printed. The automated microscope enables Z motion of the slide and the motorized stage enables its X-Y motions. The microscope also includes motorized filter turret containing fluorescence filters.

Indications for use

The ScanView System is an automated scanning microscope and image analysis system. It is intended for *in vitro* diagnostic use as an aiding tool to the pathologist or cytogeneticist in the detection, classification and enumeration of cells of interest based on color, intensity, size, pattern, and shape. The ScanView is indicated as an accessory to the following FDA cleared/approved devices to detect the following cell types:

1. CEP® X Spectrum Orange™/CEP® Y Spectrum Green™ DNA Probe Kit and is limited to the analysis of CEP XY probes via high magnification capture and analysis of interphase nuclei. CEP XY is indicated for use to assess the effectiveness of bone marrow transplantation in opposite-sex transplants.
2. Human breast cancer containing the HER-2/neu gene labeled in Red and the centromere of chromosome 17 labeled in Green via fluorescence *in situ* hybridization (FISH) in interphase nuclei from formalin-fixed, paraffin embedded human breast cancer tissue specimens with Vysis® PathVysion™ HER-2 DNA Probe kit. Results from the PathVysion™ Kit are intended for use as an adjunct to existing clinical and pathologic information used as prognostic factors in stage II, node-positive breast cancer patients. The PathVysion™ kit is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node positive breast cancer, treated with adjuvant cyclophosphamide, doxorubicin, and 5-fluorouracil (CAF) chemotherapy.
3. Cells in urine specimens, stained by fluorescence *in situ* hybridization (FISH) using Vysis UroVysion™ Bladder Cancer Kit to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus, from persons with hematuria suspected of having bladder cancer. The results are intended for use, in conjunction with and not in lieu of current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

The ScanView System is to be used as an adjunctive automated enumeration tool in conjunction with manual visualization.

Safety & Effectiveness

The device has been designed, verified and validated complying with 21CFR 820.30 regulations. Performance test data demonstrate that the device meets the required specifications. No adverse affects have been detected.

Substantial Equivalency

It is Applied Spectral Imaging Ltd. opinion that the ScanView is substantially equivalent in terms of safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

OCT 19 2011

Applied Spectral Imaging, LTD
c/o Mr. Dan Laor
6 Sireni
Haifa
Israel 10551

Re: k110345
Trade/Device Name: ScanView
Regulation Number: 21 CFR §866.4700
Regulation Name: Automated fluorescence *in situ* hybridization (FISH) enumeration systems
Regulatory Class: Class II
Product Code: NTH
Dated: September 21, 2011
Received: September 23, 2011

Dear Mr. Laor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

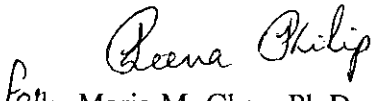
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k110345

Device Name: ScanView System

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Prescription Use: **YES** AND/OR Over-the-Counter Use: NO
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K K110345